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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,440	03/04/2002	Grant McFadden	MDSP-P01-002	3416

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EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/090,440

Applicant(s)

MCFADDEN ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/12/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-25 and 38 are pending and under consideration. The species election requirement set forth in the Office action mailed on 11/1/2004 is withdrawn, and search is expended.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This Office action contains new grounds of rejection.

Sequence Rules, Withdrawn

The objection of specification is withdrawn in view of the amendment.

Claim Objections, Withdrawn

The objection of claim 25 is withdrawn in view of the amendment

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims 1-25 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claims 1-4, 8, and 10-23 under 35 U.S.C. 102(b) as being anticipated by Yin et al., (CN of IDS filed on 02/14/2005, 1994, Nature vol. 369, pages 321-3) is withdrawn because Yin reference is about method using BAX and the amended claims no longer recite BAX, and Yin reference does not teach BAX and M11L form a complex.

The rejection of claims 1-25 under 35 U.S.C. 102(b) as being anticipated by US 5622852 A (22 April 1997, the '852 patent from now on) is also withdrawn because the amended claims are no longer anticipated by the art of record.

Double Patenting, Withdrawn

The rejection of claim 25 under 37 CFR 1.75 as being a substantial duplicate of claim 24 is withdrawn in view of the amendment.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8, 9, and 23 are rejected under 35 U.S.C. 102(a) as being anticipated by Everett et al., IDS, #CQ filed on 08/12/2005, J Exp Med. 2000 May 1;191(9):1487-98.

Claims 1-3, 8, 9, and 23 are drawn to method of screening a potential anti- or pro-apoptotic agent using M11L protein complex as the main active ingredient in a reaction mixture, wherein the testing involves affecting an enzymatic activity of the complex, wherein said agent is a natural product (claim 2, and 3), wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity (claim 8) in whole cells (claim 9), or a cell (claim 23).

Everett et al., teach method of screening a potential anti- or pro-apoptotic agent using M11L protein complex as the main active ingredient in a reaction mixture, wherein the testing involves affecting an enzymatic activity of the complex, wherein said agent is a natural product (i.e. staurosporine, which inherently is a natural product isolated from bacterium *Streptomyces staurosporeus* according to the information "Staurosporine" downloaded from the website [http, freespace.virgin.net](http://freespave.virgin.net) on 10/4/2005), wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity. Note Fig. 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Everett et al., (cited above) in view of U.S. PAT. 5,622,852 of record.

Claims 1, 4-22, 24, 25, and 38 are to method of screening a potential anti- or pro-apoptotic agent using M11L protein complex as the main active ingredient in a reaction mixture, wherein the testing involves affecting an enzymatic activity of the complex, wherein said agent is anything from various collections (claims 4-7), wherein claims 9, and 23-25 are drawn to testing involving in whole cell, more specially a yeast two hybrid system (ITS) in claims 24 and 25, and claim 10-22 are drawn to cell-free testing system (claims 10, 11, 20) of lysate, derived from mammalian cells (claim 22), wherein the

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lysate containing a recombinantly made protein (claim 21), with various degrees of protein purity (claim 12, and 13), and the protein or agent being used is immobilized on a solid support (claim 14, 16) by an antibody or biotin (claim 15), wherein the complex of the base claims containing BAX.

Everett et al., teach method of screening a potential anti- or pro-apoptotic agent using M11L protein complex as the main active ingredient in a reaction mixture.

Everett et al., do not teach the limitations of claims 4-22, 24, and 25. However, the '852 patent (at Fig. 3a, 11, 15, columns 3, 4, 39-60) teach method of screening a potential anti- or pro-apoptotic agent that binds to BAX protein in a reaction mixture, wherein said agent is polypeptide or at least 10 to 10,1000 polypeptides, wherein the method involves further testing of the agent to see whether the agent possess the ability of possessing pro- or anti-apoptotic activity, in a cell and a testing system involving in whole cell, more specially a yeast two hybrid system (ITS) or reverse yeast two hybrid system in and cell-free testing system of lysate, derived from mammalian cells, wherein the lysate containing a recombinantly made protein, with various degrees of protein purity, and the protein or agent being used is immobilized on a solid support by an antibody or biotin. In other words, the each of the limitations in the instant claims are well known techniques for screening potentially useful anti- or pro-apoptotic agents.

Therefore, it would have been obvious to use the art-known procedures and/or library compounds to screening useful compounds with a reasonable expectation of success. One of ordinary skill would have been motivate to use already known procedures and/or compounds in order to save time and effort, thus saving money.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
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A handwritten signature in black ink, appearing to read "Misook Yu", is written below the printed name and title.